



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM42/1216

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/796,578	02/06/97	012	HARRISON, R	1617 12/16/98
First Named Applicant	DRIZEN,	35 USC 154 (b) term ext. =		0 Days.

TITLE OF  
INVENTION TOPICAL DRUG PREPARATIONS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEES DUE	DATE DUE
1 22890-XX	424-488.000	M78	UTILITY	YES	\$605.00	03/16/99

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.  
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS  
APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.

Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

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Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY/DOCKET NO.
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GARY M. NATH, ESQ.  
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HM42/1216

 HA [EXAMINER], R

ART UNIT 617	PAPER NUMBER
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**DATE MAILED:**

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Notice of Allowability</b>	Application No. <b>08/796,578</b>	Applicant(s) <b>Drizen et al</b>
	Examiner <b>Robert H. Harrison</b>	Group Art Unit <b>1617</b>

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

This communication is responsive to applicants amendment, decl. & 2 mo. ext. all filed as of 12/1/98.

The allowed claim(s) is/are 1, 3-9, and 29-36.

The drawings filed on \_\_\_\_\_ are acceptable.

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

Applicant MUST submit NEW FORMAL DRAWINGS

because the originally filed drawings were declared by applicant to be informal.

including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. \_\_\_\_\_.

including changes required by the proposed drawing correction filed on \_\_\_\_\_, which has been approved by the examiner.

including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

**Attachment(s)**

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

Interview Summary, PTO-413

Examiner's Amendment/Comment

Examiner's Comment Regarding Requirement for Deposit of Biological Material

Examiner's Statement of Reasons for Allowance

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### EXAMINER'S AMENDMENT

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on December 15, 1998, Gary M. Nath requested an extension of time for <sup>additional</sup> one MONTH(S) and authorized the Commissioner to charge Deposit Account No. 14-0112 the required fee of \$435.00 - \$190.00 = #245.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

*RH&  
12/15/98*

2. The application has been amended as follows:

#### IN THE CLAIMS

- Please cancel non-elected claims 10, 12-21, 23-28, 37, and 39-44.

3. The following is an examiner's statement of reasons for allowance:

The declaration under 37 CFR 1.132 filed December 1, 1998 is sufficient to overcome the rejection of claims 1, 3-9, and 29-36 based upon Leshchiner et al. The examiner has also

*12/16/1998 TSUGGS 00000001 140112 08796578* reviewed all of the evidence of record and essentially agrees with applicants that '724 fails to

*01 FC:216 245.00 CH* teach or suggest the instant invention comprising sodium hyaluronate. Moreover, '724 teaches

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the gel slurries comprising the gel forming polymer is made from a highly crosslinked hyaluronic acid. Further, as stated by declarant, the patentees do not contemplate topical or transdermal delivery of actives or of a composition capable of being topically administered to an animal. The issue of formality (molecular weight) directed to the claimed polymers are withdrawn in view of applicants citation of page 4, lines 2-24 that evidences the non-critical nature of the molecular weight limitations.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert H. Harrison whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Thursday from 7:30 a.m. to 6:00 p.m. EST.

The fax phone number for most official papers or communications to Technology Center 1600/2900 - Group 1610 - Art Unit 1617 is (703) 308-4556. Such papers or communications must conform with the notice published in the Official Gazette, 1096 OG 30; November 15, 1989.

The fax phone number for informal or unofficial communications (i.e., proposed claim(s) or amendment(s), and/or an outline of an upcoming interview) is (703) 308-7924. The support staff is not responsible for forwarding these communications to the examiner.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group 1610 receptionist whose telephone number is (703) 308-1234.

*Robert H. Harrison*  
**Robert H. Harrison**  
**Primary Examiner**  
**Tech. Center 1600/2900**  
**Group 1610**  
**Art Unit 1617**

RHHarrison/rhh  
December 15, 1998